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**Sent:** 11/16/2012 8:02:34 PM  
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**Subject:** NEWS UPDATES: Industry, Environmental Groups Disagree On Strategies to Improve IRIS Program (BNA)

## **Industry, Environmental Groups Disagree On Strategies to Improve IRIS Program** By Patrick Ambrosio

Representatives from the chemical industry, state regulatory agencies, and environmental groups speaking at a public meeting said that the Environmental Protection Agency's chemical risk assessment program needs to be overhauled but disagreed over what reforms are needed.

Panelists at the Nov. 13 meeting hosted by EPA agreed the agency needs to improve its Integrated Risk Information System (IRIS) program to increase the frequency at which chemical assessments are completed and issued.

Richard Denison, a senior scientist at the Environmental Defense Fund, said the IRIS program has failed to meet a 2009 goal to complete most or all assessments within 23 months. No assessments issued since 2009 have met that goal, with the program also failing to meet any established deadlines for individual steps in the IRIS program, according to Denison.

Denison said those delays have "profound real-world consequences" because regulatory decisions that rely on IRIS assessments also are delayed.

Chuck Elkins, president of Chuck Elkins and Associates, said the IRIS program has "a huge deficit" when it comes to issuing final assessments and any reforms should be made with the goal of finalizing assessments much more quicker than currently happens.

### **EPA Sought Outside Views**

EPA hosted the meeting to hear outside views of the IRIS program, including scheduled changes that aim to improve the program.

Kenneth Olden, director of EPA's National Center for Environmental Assessment, said in September that the agency plans to solicit advice from all parties, including the chemical industry, environmental health advocates, and communities who may be affected by polluted sites, before moving forward with an IRIS assessment ([180 DEN A-8, 9/18/12](#)).

Those parties will be asked for advice on what studies should be used, what health problems should be focused on, and what data gaps are present before the assessment is launched, according to Olden. Currently, EPA does not solicit comment until a draft IRIS assessment is released.

Mary Fox, an assistant professor at Johns Hopkins Bloomberg School of Public Health, said more timely IRIS assessments are needed "to do the work and make the decisions on the ground every day."

She said decisionmakers, including state regulatory agencies, need regularly updated chemical assessments that keep up with the most current science.

Fox suggested that EPA look into realizing some time efficiencies, including conducting some reviews simultaneously or in parallel, rather than sequentially. Public comments could be consolidated and assessed in an integrated manner in order to speed up the IRIS process, according to Fox.

Fox also said putting assessments through two rounds of interagency review "seems redundant." She cited a need for "increased transparency" on the interagency reviews.

Currently, EPA consults with the White House and other federal agencies on draft IRIS assessments, as well as on the final, revised assessment.

### **Varied Approach Suggested**

Linda Birnbaum, director of the National Institute of Environmental Health Sciences and National Toxicology Program, suggested that EPA take a varied approach to IRIS assessments.

"I do not think there should be a one-size-fits-all approach for all IRIS assessments," she said.

Birnbaum said for certain chemicals, EPA could move "relatively rapidly" to address some exposures that are not of concern. This would give the agency more time to focus on more complicated exposures, she said.

David Fischer, senior director of the American Chemistry Council, described the announced changes to IRIS as "relatively modest" and said more enhancements are needed to improve the scientific quality of assessments and the pace by which assessments are issued.

Fischer said more transparency is needed, including EPA sharing the criteria used in the assessment and the weight of evidence decision, to improve the IRIS program. He said it is impossible for the chemical industry to reproduce an IRIS assessment unless the criteria of the assessment are known.

Fischer also said interested parties should be given the time to present comments to and have a dialogue with peer review panels convened to review the IRIS assessments. He cited EPA's recent decision to convert "listening sessions" held on IRIS assessments to allow for active dialogue between agency officials and interested parties as a model for improving engagement with peer review panels.

### **ACC Support Olden's Proposal**

ACC supports Olden's proposal to solicit advice on scoping and problem formulation before launching an assessment, Fischer said. He said other "quick fixes" to improve the program could include posting all IRIS

documents to a docket on <http://www.regulations.gov> and either applying a systematic approach to data evaluation and weight of evidence or providing a rationale for not doing so for all IRIS assessments under way.

Elkins said additional engagement would go “a long way toward compensating” for other flaws in the IRIS program. He said most delays in finalizing IRIS assessments appear to be the result of needing to conduct assessments multiple times.

Elkins said that “doing it right the first time” is one model that could reduce the amount of time it takes for the IRIS program to generate an assessment.

He also recommended that the agency conduct the IRIS program “in a fishbowl,” with all documents placed in a public docket, including recordings of every meeting that takes place between interested parties and EPA staff.

#### **Fewer Comment Periods Needed, Scientist Says**

Denison called on EPA to consolidate opportunities for public input during the IRIS process. He suggested that the agency solicit input at the beginning of the process and once a draft assessment is completed.

Denison said a “more involved process” not only leads to delays in finalizing assessments but also “virtually ensures the input received by EPA is imbalanced.”

Chemical manufacturers and trade associations have a clear financial interest in the outcome of each IRIS assessment, so they take advantage of every opportunity for input allowed, according to Denison.

“We must simply stop pretending that there is a level playing field,” he said. “It is a certitude that the affected industry will be better represented than other stakeholders at each opportunity for input, and the more such opportunities, the greater the imbalance becomes.”

Gloria Post, a research scientist at the New Jersey Department of Environmental Protection, said that EPA must be aware that many interested parties, including state regulatory agencies, may not have the resources needed to fully participate in the IRIS process.

Post said states are “very short staffed” and are unable to submit multiple rounds of written comments on a single chemical assessment. Reviewing IRIS assessments are “a very small part of the work” done by state environmental agencies, while other parties may have staff members dedicated to dealing with IRIS issues, Post said.

Post recommended that EPA provide funding for states that have interest and relative expertise to participate in the IRIS process. Post also said the agency could provide online or in-person training for state risk assessors on new IRIS processes, which she said are “technically complex.”

#### **Environmental Groups Oppose Advisory Panel Reform**

Denison also expressed opposition to the EPA Science Advisory Board Reform Act of 2012 (H.R. 6564), which he said is part of a “chemical industry assault on independent government science.”

The bill, introduced in October by Republican members of the House Science, Space, and Technology Committee, would limit the ability of the Science Advisory Board to offer policy advice to EPA and place limits on the number of agency grant or contract recipients who could serve on the board at one time ([190 DEN A-3, 10/2/12](#)).

The legislation proposes that at least 10 percent of the advisory board be made up of representatives of state, local, or tribal governments and to allow a maximum of 10 percent of members to be recipients of financial assistance from EPA.

Denison said the bill would exclude scientists who receive government research funding. Supporters of the bill falsely claim that government funding creates a conflict of interest, according to Denison.

Jennifer Sass, a senior scientist with the Natural Resources Defense Council, described the legislation as “part of a coordinated chemical industry attack” on EPA science and scientists that receive federal funding. She said participation of members of the academic community who receive funding from EPA or other federal agencies is “critical” to the peer review process and operations of the scientific advisory board.

Fischer said ACC is “very, very supportive of” the reform bill. The industry group believes the legislation will strengthen the advisory board's process for reviewing scientific assessments, Fischer said.

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